

**Calendar No. 518**

110TH CONGRESS  
1ST SESSION

**S. 1382**

To amend the Public Health Service Act to provide for the establishment  
of an Amyotrophic Lateral Sclerosis Registry.

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IN THE SENATE OF THE UNITED STATES

MAY 14, 2007

Mr. REID (for himself, Mrs. MURRAY, Mrs. BOXER, Mr. HARKIN, Mr. BROWN, Mr. ISAKSON, Mr. INOUE, Mr. DURBIN, Mr. SANDERS, Mr. CRAIG, Mr. BAUCUS, Mr. REED, Mrs. FEINSTEIN, Mr. COLEMAN, Mr. COCHRAN, Mr. CONRAD, Mrs. CLINTON, Mr. MENENDEZ, Mr. THUNE, Mr. BUNNING, Ms. MURKOWSKI, Mrs. DOLE, Mr. JOHNSON, Ms. KLOBUCHAR, Mr. BURR, Mr. DODD, Mr. NELSON of Florida, Mr. BAYH, Mr. HAGEL, Mr. LAUTENBERG, Mr. VITTER, Mr. WARNER, Mr. SCHUMER, Mr. BINGAMAN, Mr. LOTT, Mr. DEMINT, Mr. BENNETT, Ms. SNOWE, Mr. DORGAN, Ms. STABENOW, Mr. MARTINEZ, Mr. CASEY, Mr. GRAHAM, Mr. TESTER, Mr. SMITH, Mr. LIEBERMAN, Mr. WHITEHOUSE, Mr. CARDIN, Mr. AKAKA, Mr. GRASSLEY, Ms. CANTWELL, Ms. COLLINS, Ms. LANDRIEU, Mr. WYDEN, Ms. MIKULSKI, Mr. BROWNBACK, Mr. SESSIONS, Mr. BIDEN, Mr. KERRY, Mr. LEAHY, Mr. CHAMBLISS, Mrs. MCCASKILL, Mr. LEVIN, Mr. CARPER, Mr. PRYOR, Mr. SUNUNU, and Mrs. LINCOLN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

DECEMBER 4, 2007

Reported by Mr. KENNEDY, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]

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**A BILL**

To amend the Public Health Service Act to provide for

the establishment of an Amyotrophic Lateral Sclerosis Registry.

1       *Be it enacted by the Senate and House of Representa-*  
 2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “ALS Registry Act”.

5       **SEC. 2. FINDINGS.**

6       Congress makes the following findings:

7               (1) Amyotrophic lateral sclerosis (referred to in  
 8       this section as “ALS”) is a fatal, progressive  
 9       neurodegenerative disease that affects motor nerve  
 10      cells in the brain and the spinal cord.

11              (2) The average life expectancy for a person  
 12      with ALS is 2 to 5 years from the time of diagnosis.

13              (3) The cause of ALS is not well understood.

14              (4) There is only one drug currently approved  
 15      by the Food and Drug Administration for the treat-  
 16      ment of ALS, which has thus far shown only modest  
 17      effects, prolonging life by just a few months.

18              (5) There is no known cure for ALS.

19              (6) More than 5,000 individuals in the United  
 20      States are diagnosed with ALS annually and as  
 21      many as 30,000 individuals may be living with ALS  
 22      in the United States today.

1           (7) Studies have found relationships between  
2           ALS and environmental and genetic factors, but  
3           those relationships are not well understood.

4           (8) Scientists believe that there are significant  
5           ties between ALS and other motor neuron diseases.

6           (9) Several ALS disease registries and data-  
7           bases exist in the United States and throughout the  
8           world, including the SOD1 database, the National  
9           Institute of Neurological Disorders and Stroke re-  
10          pository, and the Department of Veterans Affairs  
11          ALS Registry.

12          (10) A single national system to collect and  
13          store information on the prevalence and incidence of  
14          ALS in the United States does not exist.

15          (11) In each of fiscal years 2006 and 2007,  
16          Congress directed \$887,000 to the Centers for Dis-  
17          ease Control and Prevention to begin a nationwide  
18          ALS registry.

19          (12) The Centers for Disease Control and Pre-  
20          vention and the Agency for Toxic Substances and  
21          Disease Registry has established three pilot projects,  
22          beginning in fiscal year 2006, to evaluate the science  
23          to guide the creation of a national ALS registry.

24          (13) The establishment of a national registry  
25          will help—

1           (A) to identify the incidence and preva-  
2           lence of ALS in the United States;

3           (B) to collect data important to the study  
4           of ALS;

5           (C) to promote a better understanding of  
6           ALS;

7           (D) to collect information that is impor-  
8           tant for research into the genetic and environ-  
9           mental factors that cause ALS;

10          (E) to strengthen the ability of a clearing-  
11          house—

12               (i) to collect and disseminate research  
13               findings on environmental, genetic and  
14               other causes of ALS and other motor neu-  
15               ron disorders that can be confused with  
16               ALS, misdiagnosed as ALS, and in some  
17               cases progress to ALS;

18               (ii) make available information to pa-  
19               tients about research studies for which  
20               they may be eligible; and

21               (iii) maintain information about clin-  
22               ical specialists and clinical trials on thera-  
23               pies; and

24          (F) to enhance efforts to find treatments  
25          and a cure for ALS.

1 **SEC. 3. AMENDMENT TO THE PUBLIC HEALTH SERVICE**  
 2 **ACT.**

3 Part P of title III of the Public Health Service Act  
 4 (42 U.S.C. 280g et seq.) is amended by adding at the end  
 5 the following:

6 **“SEC. 399R. AMYOTROPHIC LATERAL SCLEROSIS REG-**  
 7 **ISTRY.**

8 **“(a) ESTABLISHMENT.—**

9 **“(1) IN GENERAL.—**Not later than 1 year after  
 10 the receipt of the report described in subsection  
 11 (b)(2)(A), the Secretary, acting through the Director  
 12 of the Centers for Disease Control and Prevention  
 13 and in consultation with a national voluntary health  
 14 organization with experience serving the population  
 15 of individuals with amyotrophic lateral sclerosis (re-  
 16 ferred to in this section as ‘ALS’), shall—

17 **“(A) develop a system to collect data on**  
 18 **ALS and other motor neuron disorders that can**  
 19 **be confused with ALS, misdiagnosed as ALS,**  
 20 **and in some cases progress to ALS, including**  
 21 **information with respect to the incidence and**  
 22 **prevalence of the disease in the United States;**  
 23 **and**

24 **“(B) establish a national registry for the**  
 25 **collection and storage of such data to include a**  
 26 **population-based registry of cases in the United**

1 States of ALS and other motor neuron dis-  
 2 orders that can be confused with ALS,  
 3 misdiagnosed as ALS, and in some cases  
 4 progress to ALS.

5 “(2) PURPOSE.—It is the purpose of the reg-  
 6 istry established under paragraph (1)(B) to gather  
 7 available data concerning—

8 “(A) ALS, including the incidence and  
 9 prevalence of ALS in the United States;

10 “(B) the environmental and occupational  
 11 factors that may be associated with the disease;

12 “(C) the age, race or ethnicity, gender, and  
 13 family history of individuals who are diagnosed  
 14 with the disease;

15 “(D) other motor neuron disorders that  
 16 can be confused with ALS, misdiagnosed as  
 17 ALS, and in some cases progress to ALS; and

18 “(E) other matters as recommended by the  
 19 Advisory Committee established under sub-  
 20 section (b).

21 “(b) ADVISORY COMMITTEE.—

22 “(1) ESTABLISHMENT.—Not later than 90 days  
 23 after the date of the enactment of this section, the  
 24 Secretary, acting through the Director of the Cen-  
 25 ters for Disease Control and Prevention, shall estab-

lish a committee to be known as the Advisory Committee on the National ALS Registry (referred to in this section as the ‘Advisory Committee’). The Advisory Committee shall be composed of at least one member, to be appointed by the Secretary, acting through the Director of the Centers for Disease Control and Prevention, representing each of the following:

“(A) National voluntary health associations that focus solely on ALS and have demonstrated experience in ALS research, care, and patient services, as well as other voluntary associations focusing on neurodegenerative diseases that represent and advocate on behalf of patients with ALS and patients with other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS.

“(B) The National Institutes of Health, to include, upon the recommendation of the Director of the National Institutes of Health, representatives from the National Institute of Neurological Disorders and Stroke and the National Institute of Environmental Health Sciences.

“(C) The Department of Veterans Affairs.

1           “(D) The Agency for Toxic Substances  
2           and Disease Registry.

3           “(E) The Centers for Disease Control and  
4           Prevention.

5           “(F) Patients with ALS or their family  
6           members.

7           “(G) Clinicians with expertise on ALS and  
8           related diseases.

9           “(H) Epidemiologists with experience in  
10          data registries.

11          “(I) Geneticists or experts in genetics who  
12          have experience with the genetics of ALS or  
13          other neurological diseases.

14          “(J) Statisticians.

15          “(K) Ethicists.

16          “(L) Attorneys.

17          “(M) Other individuals with an interest in  
18          developing and maintaining the National ALS  
19          Registry.

20          “(2) DUTIES.—The Advisory Committee shall  
21          review information and make recommendations to  
22          the Secretary concerning—

23                 “(A) the development and maintenance of  
24                 the National ALS Registry;



1           “(B) the type of information to be col-  
2           lected and stored in the Registry;

3           “(C) the manner in which such data is to  
4           be collected;

5           “(D) the use and availability of such data  
6           including guidelines for such use; and

7           “(E) the collection of information about  
8           diseases and disorders that primarily affect  
9           motor neurons that are considered essential to  
10          furthering the study and cure of ALS.

11          “(3) REPORT.—Not later than 1 years after the  
12          date on which the Advisory Committee is estab-  
13          lished, the Advisory Committee shall submit a report  
14          concerning the review conducted under paragraph  
15          (2) that contains the recommendations of the Advi-  
16          sory Committee with respect to the results of such  
17          review.

18          “(e) GRANTS.—Notwithstanding the recommenda-  
19          tions of the Advisory Committee under subsection (b), the  
20          Secretary, acting through the Director of the Centers for  
21          Disease Control and Prevention, may award grants to, and  
22          enter into contracts and cooperative agreements with, pub-  
23          lic or private nonprofit entities for the collection, analysis,  
24          and reporting of data on ALS and other motor neuron

1 disorders that can be confused with ALS, misdiagnosed  
 2 as ALS, and in some cases progress to ALS.

3       “(d) COORDINATION WITH STATE, LOCAL, AND FED-  
 4 ERAL REGISTRIES.—

5           “(1) IN GENERAL.—In establishing the Na-  
 6 tional ALS Registry under subsection (a), the Sec-  
 7 retary, acting through the Director of the Centers  
 8 for Disease Control and Prevention, shall—

9           “(A) identify, build upon, expand, and co-  
 10 ordinate among existing data and surveillance  
 11 systems, surveys, registries, and other Federal  
 12 public health and environmental infrastructure  
 13 wherever possible, including—

14           “(i) the 3 ALS registry pilot projects  
 15 initiated in fiscal year 2006 by the Centers  
 16 for Disease Control and Prevention and  
 17 the Agency for Toxic Substances and Dis-  
 18 ease Registry at the South Carolina Office  
 19 of Research & Statistics; the Mayo Clinic  
 20 in Rochester, Minnesota; and Emory Uni-  
 21 versity in Atlanta, Georgia;

22           “(ii) the Department of Veterans Af-  
 23 fairs ALS Registry;

24           “(iii) the DNA and Cell Line Reposi-  
 25 tory of the National Institute of Neuro-

logical Disorders and Stroke Human Genetics Resource Center;

“(iv) Agency for Toxic Substances and Disease Registry studies, including studies conducted in Illinois, Missouri, El Paso and San Antonio, Texas, and Massachusetts;

“(v) State-based ALS registries, including the Massachusetts ALS Registry;

“(vi) the National Vital Statistics System; and

“(vii) any other existing or relevant databases that collect or maintain information on those motor neuron diseases recommended by the Advisory Committee established in subsection (b); and

“(B) provide for research access to ALS data as recommended by the Advisory Committee established in subsection (b) to the extent permitted by applicable statutes and regulations and in a manner that protects personal privacy consistent with applicable privacy statutes and regulations.

“(2) COORDINATION WITH NIH AND DEPARTMENT OF VETERANS AFFAIRS.—Notwithstanding the

1 recommendations of the Advisory Committee estab-  
 2 lished in subsection (b), and consistent with applica-  
 3 ble privacy statutes and regulations, the Secretary  
 4 shall ensure that epidemiological and other types of  
 5 information obtained under subsection (a) is made  
 6 available to the National Institutes of Health and  
 7 the Department of Veterans Affairs.

8 “(e) DEFINITION.—For the purposes of this section,  
 9 the term ‘national voluntary health association’ means a  
 10 national non-profit organization with chapters or other af-  
 11 filiated organizations in States throughout the United  
 12 States.

13 “(f) AUTHORIZATION OF APPROPRIATIONS.—There  
 14 are authorized to be appropriated to carry out this section,  
 15 \$25,000,000 for fiscal year 2008, and such sums as may  
 16 be necessary for each of fiscal years 2009 through 2012.”.

17 **SECTION 1. SHORT TITLE.**

18 *This Act may be cited as the “ALS Registry Act”.*

19 **SEC. 2. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT.**

20 *Part P of title III of the Public Health Service Act*  
 21 *(42 U.S.C. 280g et seq.) is amended by adding at the end*  
 22 *the following:*

23 **“SEC. 399R. AMYOTROPHIC LATERAL SCLEROSIS REGISTRY.**

24 “(a) ESTABLISHMENT.—

1           “(1) *IN GENERAL.*—Not later than 1 year after  
2     the receipt of the report described in subsection  
3     (b)(2)(A), the Secretary, acting through the Director  
4     of the Centers for Disease Control and Prevention,  
5     shall—

6           “(A) develop a system to collect data on  
7     amyotrophic lateral sclerosis (referred to in this  
8     section as ‘ALS’) and other motor neuron dis-  
9     orders that can be confused with ALS,  
10    misdiagnosed as ALS, and in some cases  
11    progress to ALS, including information with re-  
12    spect to the incidence and prevalence of the dis-  
13    ease in the United States; and

14          “(B) establish a national registry for the  
15    collection and storage of such data to develop a  
16    population-based registry of cases in the United  
17    States of ALS and other motor neuron disorders  
18    that can be confused with ALS, misdiagnosed as  
19    ALS, and in some cases progress to ALS.

20          “(2) *PURPOSE.*—It is the purpose of the registry  
21    established under paragraph (1)(B) to—

22          “(A) better describe the incidence and prev-  
23    alence of ALS in the United States;

1           “(B) examine appropriate factors, such as  
2           environmental and occupational, that may be as-  
3           sociated with the disease;

4           “(C) better outline key demographic factors  
5           (such as age, race or ethnicity, gender, and fam-  
6           ily history of individuals who are diagnosed  
7           with the disease) associated with the disease;

8           “(D) better examine the connection between  
9           ALS and other motor neuron disorders that can  
10          be confused with ALS, misdiagnosed as ALS,  
11          and in some cases progress to ALS; and

12          “(E) other matters as recommended by the  
13          Advisory Committee established under subsection  
14          (b).

15          “(b) ADVISORY COMMITTEE.—

16               “(1) ESTABLISHMENT.—Not later than 180 days  
17               after the date of the enactment of this section, the Sec-  
18               retary, acting through the Director of the Centers for  
19               Disease Control and Prevention, shall establish a  
20               committee to be known as the Advisory Committee on  
21               the National ALS Registry (referred to in this section  
22               as the ‘Advisory Committee’). The Advisory Com-  
23               mittee shall be composed of not more than 27 mem-  
24               bers to be appointed by the Secretary, acting through

1       *the Centers for Disease Control and Prevention, of*  
2       *which—*

3               “(A) *two-thirds of such members shall rep-*  
4       *resent governmental agencies—*

5               “(i) *including at least one member rep-*  
6       *resenting—*

7               “(I) *the National Institutes of*  
8       *Health, to include, upon the rec-*  
9       *ommendation of the Director of the Na-*  
10       *tional Institutes of Health, representa-*  
11       *tives from the National Institute of*  
12       *Neurological Disorders and Stroke and*  
13       *the National Institute of Environ-*  
14       *mental Health Sciences;*

15               “(II) *the Department of Veterans*  
16       *Affairs;*

17               “(III) *the Agency for Toxic Sub-*  
18       *stances and Disease Registry; and*

19               “(IV) *the Centers for Disease Con-*  
20       *trol and Prevention; and*

21               “(ii) *of which at least one such member*  
22       *shall be a clinician with expertise on ALS*  
23       *and related diseases, an epidemiologist with*  
24       *experience in data registries, a statistician,*  
25       *an ethicist, and a privacy expert (relating*

1           to the privacy regulations under the Health  
 2           Insurance Portability and Accountability  
 3           Act of 1996); and

4           “(B) one-third of such members shall be  
 5           public members, including at least one member  
 6           representing—

7                   “(i) national and voluntary health as-  
 8                   sociations;

9                   “(ii) patients with ALS or their fam-  
 10                  ily members;

11                  “(iii) clinicians with expertise on ALS  
 12                  and related diseases;

13                  “(iv) epidemiologists with experience  
 14                  in data registries;

15                  “(v) geneticists or experts in genetics  
 16                  who have experience with the genetics of  
 17                  ALS or other neurological diseases and

18                  “(vi) other individuals with an interest  
 19                  in developing and maintaining the Na-  
 20                  tional ALS Registry.

21           “(2) DUTIES.—The Advisory Committee shall re-  
 22           view information and make recommendations to the  
 23           Secretary concerning—

24                   “(A) the development and maintenance of  
 25                  the National ALS Registry;



1           “(B) the type of information to be collected  
2           and stored in the Registry;

3           “(C) the manner in which such data is to  
4           be collected;

5           “(D) the use and availability of such data  
6           including guidelines for such use; and

7           “(E) the collection of information about dis-  
8           eases and disorders that primarily affect motor  
9           neurons that are considered essential to fur-  
10          thering the study and cure of ALS.

11          “(3) REPORT.—Not later than 270 days after the  
12          date on which the Advisory Committee is established,  
13          the Advisory Committee shall submit a report to the  
14          Secretary concerning the review conducted under  
15          paragraph (2) that contains the recommendations of  
16          the Advisory Committee with respect to the results of  
17          such review.

18          “(c) GRANTS.—The Secretary, acting through the Di-  
19          rector of the Centers for Disease Control and Prevention,  
20          may award grants to, and enter into contracts and coopera-  
21          tive agreements with, public or private nonprofit entities  
22          for the collection, analysis, and reporting of data on ALS  
23          and other motor neuron disorders that can be confused with  
24          ALS, misdiagnosed as ALS, and in some cases progress to  
25          ALS after receiving the report under subsection (b)(3).

1       “(d) *COORDINATION WITH STATE, LOCAL, AND FED-*  
2 *ERAL REGISTRIES.*—

3               “(1) *IN GENERAL.*—*In establishing the National*  
4 *ALS Registry under subsection (a), the Secretary,*  
5 *acting through the Director of the Centers for Disease*  
6 *Control and Prevention, shall—*

7                       “(A) *identify, build upon, expand, and co-*  
8 *ordinate among existing data and surveillance*  
9 *systems, surveys, registries, and other Federal*  
10 *public health and environmental infrastructure*  
11 *wherever possible, which may include—*

12                               “(i) *any registry pilot projects pre-*  
13 *viously supported by the Centers for Disease*  
14 *Control and Prevention;*

15                               “(ii) *the Department of Veterans Af-*  
16 *fairs ALS Registry;*

17                               “(iii) *the DNA and Cell Line Reposi-*  
18 *tory of the National Institute of Neuro-*  
19 *logical Disorders and Stroke Human Genet-*  
20 *ics Resource Center at the National Insti-*  
21 *tutes of Health;*

22                               “(iv) *Agency for Toxic Substances and*  
23 *Disease Registry studies, including studies*  
24 *conducted in Illinois, Missouri, El Paso and*  
25 *San Antonio, Texas, and Massachusetts;*

1 “(v) *State-based ALS registries;*

2 “(vi) *the National Vital Statistics Sys-*  
3 *tem; and*

4 “(vii) *any other existing or relevant*  
5 *databases that collect or maintain informa-*  
6 *tion on those motor neuron diseases rec-*  
7 *ommended by the Advisory Committee es-*  
8 *tablished in subsection (b); and*

9 “(B) *provide for research access to ALS*  
10 *data as recommended by the Advisory Committee*  
11 *established in subsection (b) to the extent per-*  
12 *mitted by applicable statutes and regulations*  
13 *and in a manner that protects personal privacy*  
14 *consistent with applicable privacy statutes and*  
15 *regulations.*

16 “(2) *COORDINATION WITH NIH AND DEPARTMENT*  
17 *OF VETERANS AFFAIRS.—Consistent with applicable*  
18 *privacy statutes and regulations, the Secretary shall*  
19 *ensure that epidemiological and other types of infor-*  
20 *mation obtained under subsection (a) is made avail-*  
21 *able to the National Institutes of Health and the De-*  
22 *partment of Veterans Affairs.*

23 “(e) *DEFINITION.—For the purposes of this section, the*  
24 *term ‘national voluntary health association’ means a na-*  
25 *tional non-profit organization with chapters or other affili-*

1 *ated organizations in States throughout the United States*  
 2 *with experience serving the population of individuals with*  
 3 *ALS and have demonstrated experience in ALS research,*  
 4 *care, and patient services.*

5 “(f) *AUTHORIZATION OF APPROPRIATIONS.—There are*  
 6 *authorized to be appropriated to carry out this section,*  
 7 *\$2,000,000 for fiscal year 2008, \$25,000,000 for fiscal year*  
 8 *2009, and \$16,000,000 for each of fiscal years 2010 through*  
 9 *2012.”.*

10 **SEC. 3. REPORT ON REGISTRIES.**

11 *Not later than 18 months after the date of enactment*  
 12 *of this Act, the Secretary of Health and Human Services*  
 13 *shall submit to the appropriate committees of Congress a*  
 14 *report outlining—*

- 15 *(1) the registries currently under way;*
- 16 *(2) future planned registries;*
- 17 *(3) the criteria involved in determining what*  
 18 *registries to conduct, defer, or suspend; and*
- 19 *(4) the scope of those registries.*

20 *The report shall also include a description of the activities*  
 21 *the Secretary undertakes to establish partnerships with re-*  
 22 *search and patient advocacy communities to expand reg-*  
 23 *istries.*



Calendar No. 518

110<sup>TH</sup> CONGRESS  
1<sup>ST</sup> Session

**S. 1382**

**A BILL**

To amend the Public Health Service Act to provide  
for the establishment of an Amyotrophic Lateral  
Sclerosis Registry.

DECEMBER 4, 2007

Reported with an amendment